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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/606,158	06/25/2003	J. Wallace Parce	100/00541	3563

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EXAMINER

STAFIRA, MICHAEL PATRICK

ART UNIT PAPER NUMBER

2877

DATE MAILED: 09/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/606,158

Applicant(s)

PARCE, J. WALLACE

Examiner

Michael P. Stafira

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>10/6/03; 6/25/03</u> . | 6) <input type="checkbox"/> Other: ____.  |

## DETAILED ACTION

### *Double Patenting*

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-22 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-22 of U.S. Patent No. 6,337,740. Although the conflicting claims are not identical, they are not patentably distinct from each other because using a plurality of subject material would be obvious to one skilled in the art because it allows multiple materials to be inspected, therefore decreasing the overall amount of time needed for inspection.

### *Claim Rejections - 35 USC § 102*

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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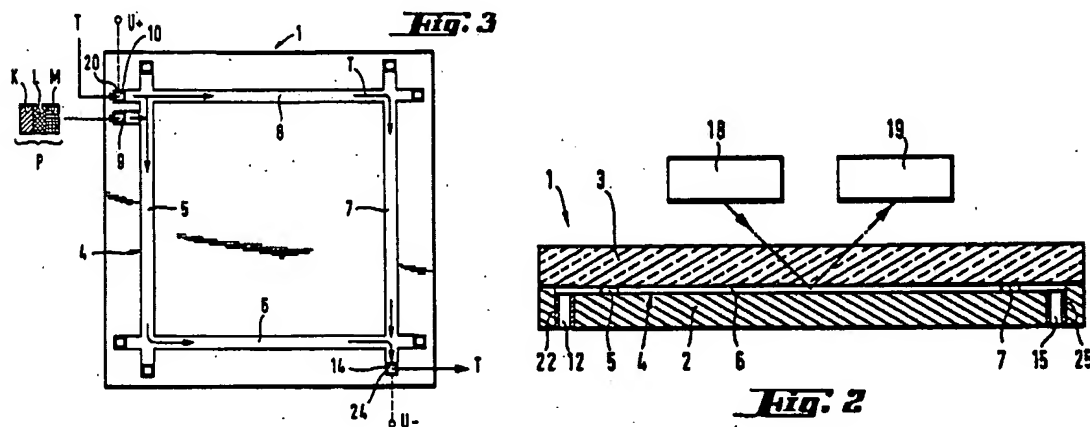
A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 2, 4, 6-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Manz ('114).

### Claim 1

Manz ('114) discloses flowing a first fluid (Fig. 3, Ref. P) comprising a series of a plurality of subject materials (Fig. 3, Ref. K, L, M) through a first microchannel (Fig. 3, Ref. 5) to a separation channel by applying pressure to the first fluid wherein the pressure is applied to the first fluid by a pressure source external to the first microchannel (Col. 8, lines 26-42); and applying an electrophoretic force to the first fluid to introduce individual ones of the plurality of subject materials into the separation channel, and to separate each of the plurality of subject materials into its respective sample components (Col. 8, lines 42-61).



### Claim 2

Manz ('114) discloses the first microchannel is present in a body structure, wherein the pressure is applied to the fluid by a micropump present in the body structure (Col. 8, lines 26-42).

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**Claim 4**

Manz ('114) further discloses each of the plurality of subject materials is separated into one or more components in the separation channel by the application of an electrophoretic force (Col. 8, lines 43-68).

**Claim 6**

Manz ('114) further discloses detecting the respective sample components of each of the plurality of subject materials (Col. 8, lines 1-25).

**Claim 7**

Manz ('114) further discloses the detecting is performed with a detector (Fig. 2, Ref. 19) mounted proximal to the separation channel (Fig. 2, Ref. 6).

**Claim 8**

The reference of Manz ('114) further discloses the detector comprising one of a photoreceptor (Col. 8, lines 10-11).

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 3, 5, 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Manz ('114).

**Claim 3**

Manz ('114) discloses the claimed invention except for the plurality of subject materials is one of nucleic acid, a chemical compound, etc.... It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Manz ('114) with one of the plurality of subject materials since it was well known in the art that using different subject materials increases the range of materials that can be inspected, therefore making the inspection apparatus more versatile in the type of application it is used.

**Claim 5**

Manz ('114) discloses the claimed invention except for the subject material comprises one or more fluorescent labeled species. It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Manz ('114) with the fluorescent labeled species since it was well known in the art that using separation channels that the materials are going to be fluorescent so as to be detectable by a sensor, therefore producing a more accurate measurement of the material.

**Claim 9**

Manz ('114) discloses the claimed invention except for analyzing signal frequency from the detector. It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Manz ('114) with the analyzing the signal frequency from the detector since it was well known in the art that analyzing the detector signal allows for a more accurate calculation of the detected signal, therefore improving the sensitivity of the measured signal.

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7. Claims 10-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Manz ('114).

**Claim 10**

Manz ('114) discloses a microfluidic device comprising a body structure comprising at least first and second intersecting microchannels fabricated therein (Fig. 3, Ref. 5, 8); a pressure source fluidly coupled to the first microchannel (Col. 8, lines 26-42); and a voltage or current controller operably coupled to the second microchannel; wherein the first microchannel is fluidly coupled to at least one source of a plurality of different subject materials (Fig. 3, Ref. K, L, M)(Col. 8, lines 42-61).

**Claim 11**

Manz ('114) discloses the pressure source is external to the body structure (Col. 8, lines 26-42).

**Claim 12**

The reference of Manz ('114) further discloses the pressure source is a micropump in the body structure (Col. 8, lines 26-42).

**Claim 13**

Manz ('114) discloses the voltage or current controller is coupled to the second microchannel via electrodes (Fig. 3, Ref. 10, 24) positioned in one or more reservoir (Fig. 3, Ref. 20), which reservoir is fluidly coupled to the second microchannel (See Fig. 3).

**Claim 14**

Manz ('114) discloses the voltage or current controller comprises a voltage controller that provides selectable voltage levels (Col. 7, lines 35-56).

**Claim 15**

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Manz ('114) discloses the device comprises reservoirs at termini (Fig. 3, Ref. 10, 14) of each of the at least two channels (Col. 8, lines 43-61).

**Claim 16**

The reference of Manz ('114) further discloses the voltage or current controller comprises a voltage controller that provides selectable voltage levels to more than one of the reservoirs (Col. 9, lines 33-53).

**Claim 17**

Manz ('114) further discloses the second microchannel comprises reservoirs at termini of the second microchannel (Fig. 3, Ref. 9-17).

**Claim 18**

Manz ('114) discloses one electrode in one of the reservoirs (Col. 8, lines 26-42).

**Claim 19**

The reference of Manz ('114) further discloses a detector mounted proximal to the second microchannel (See Fig. 2).

**Claim 20**

Manz ('114) discloses one a photoreceptor (Col. 8, lines 10-11).

8. Claims 21-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Manz ('114).

**Claim 21**

Manz ('114) discloses the claimed invention except for analyzing signal frequency from the detector. It would have been obvious to one having ordinary skill in the art at the time the



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invention was made to combine Manz ('114) with the analyzing the signal frequency from the detector since it was well known in the art that analyzing the detector signal allows for a more accurate calculation of the detected signal, therefore improving the sensitivity of the measured signal.

#### **Claim 22**

Manz ('114) discloses the claimed invention except for the frequency analyzer breaks the electrical signals into their component frequencies. It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Manz ('114) with frequency analyzer since it was well known in the art that breaking the signal into component frequencies allows for precise evaluations of the detected signal, therefore providing a more accurate measurement.

#### **Claim 23**

Manz ('114) discloses the claimed invention except for different subject materials is coupled through a electropipettor. It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Manz ('114) with the electropipettor since it was well known in the art that a electropipettor efficient movement of fluid in a microchannel, therefore reducing the likelihood the microchannel is going to clog up.

#### **Claim 24**

Manz ('114) discloses the claimed invention except for a plurality of reservoirs with different subject materials. It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Manz ('114) with the plurality of reservoirs since it was well known in the art that using a plurality of reservoirs increases the amount of material


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that can be inspected at a time, therefore decreasing the amount of time to which a samples can be inspected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael P. Stafira whose telephone number is 571-272-2430.. The examiner can normally be reached on 4/10 Schedule Mon.-Thurs..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gregory Toatley can be reached on 571-272-2800 ext. 77. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Michael P. Stafira  
Primary Examiner  
Art Unit 2877

September 15, 2006